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SUBJECT: Shenzhen High-Tech Company SiBiono on the Cutting Edge of Gene Therapy Treatment

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¶1. (SBU) SUMMARY: High-tech company SiBiono has received significant government support in its cutting-edge efforts to introduce new gene therapy medicines to treat serious diseases. The company's key product, the State Food and Drug Administration of China (SFDA)-approved anti-cancer drug Gendicine, currently has sales totaling roughly USD 3.75 million, but the company is apparently expecting business to grow as it constructs another facility that can increase production from 180,000 to 2 million doses a year. The drug had promising success rates in testing and in initial use and some experts have heralded its arrival, while others question if there was enough scientific evaluation performed before the drug was approved. Nonetheless the company has benefited from being the first to win SFDA approval; the company basically "wrote the book" on R&D and commercialization of gene therapy products in China and it was able to receive two patents covering Gendicine. Recent reports about disgraced chip developer Chen Jin reveal the lengths some Chinese will go to be the "first" to achieve a breakthrough in China, however, and we can speculate that future Chinese innovators like SiBiono may receive extra scrutiny as a result. END SUMMARY.

¶2. (SBU) Econoffs recently visited Shenzhen SiBiono GeneTech Co. Ltd. (SiBiono), manufacturer of the world's first gene therapy medicine. Econoffs, who were in Shenzhen with Embassy Economic Minister Counselor Robert Luke for other appointments, visited SiBiono to learn more about this privately-held high-tech company. The group met with Fu Chiu, assistant to the president. Fu, a polished speaker fluent in English, earned a PhD in molecular biology from the University of Chicago.

¶3. (SBU) SiBiono, located in Shenzhen's Nanshan High-tech Industrial Park, was founded in 1998 by Dr. Peng Zhaohui. Peng has a joint PhD from a university in Xian and from Japan's Chiba University. He worked at the medical school at the University of California at Los Angeles and at a biotech startup in San Diego in the mid-1990s before returning to China. He launched SiBiono in 1998 with USD

300,000 in seed money from the Shenzhen government. Since then, SiBiono has received USD 5 million from private investors and more than USD 6 million in government grants, according to Western press reports. Peng estimated in the Chinese press that one-fourth of the investment in his company's key drug came from "various government sources, including The Ministry of Science and Technology, the 863 program (a State high-tech fund), and the Shenzhen municipal government."

¶4. (SBU) SiBiono aims to become "the leading gene therapy pharmaceutical company in the world" and is committed to developing gene therapy products, according to company literature. SiBiono's major accomplishment to date is its gene therapy medicine "Recombinant Ad-p53 Anti-cancer Injection," also registered as "Gendicine." (Note: In 1999, gene therapy suffered major setbacks in the United States following the death of a patient in a clinical trial and other adverse results, causing the U.S. FDA to stop a number of trials. This created an opportunity for Chinese researchers, who without the same regulatory rules were able to take ideas that originated in the United States but stagnated there; Gendicine, for example, is similar to a gene therapy treatment that was pioneered by Texas company Introgen Therapeutics Inc., but has yet to win FDA approval, according to Western press reports. End Note.)

A Tale of Two Drugs...

¶5. (SBU) SiBiono currently has two main drugs. The first is its wide spectrum anti-cancer drug "Gendicine" which has been approved by the SFDA. The second drug targets cardiovascular disease, but this drug has not yet been

approved by the SFDA. Fu estimated that it will take two to three more years to get approval for this drug.

...But Really A One Drug Wonder

¶6. (SBU) While Fu talked briefly about the cardio vascular drug, Gendicine appears to steal the show at SiBiono. Gendicine began clinical trials in 1998 and by 2004 had been approved by the SFDA, making it the first gene therapy product approved for commercialization by a regulatory agency. Gendicine has not yet been approved anywhere outside of China, but Fu said the company is working to gain approval in Europe and in other Asian countries. As described in a Western press report, Gendicine combines a gene named p53, which suppresses tumor formation, with a modified common virus. When the product is injected into a tumor, the virus carries the gene into cancer cells. The gene then prompts the tumor cells to "commit suicide." Gendicine works best on solid cancers (tumors) including breast cancer, according to Fu.

¶7. (SBU) Sales of the drug total 30 million RMB (approximately USD 3.75 million), and by January 2006, Gendicine had been used to treat approximately 3,500 patients with more than 40 types of cancers, according to company literature. Side affects included fever, chills, pain at the injection site, discomfort, fatigue, nausea, and diarrhea.

¶8. (SBU) Gendicine is manufactured in SiBiono's Shenzhen facility. It takes approximately two months to make one batch of the drug, which equals approximately 8,000 doses. Fu said the company currently produces 180,000 doses a year in its main Shenzhen facility, but is constructing another facility that can produce 2 million doses a year. Western press reports notes that the new facility is valued at USD 20 million. A typical treatment for a patient is one dose per week for 6-8 weeks, though Fu said in certain extreme circumstances several doses per week have been administered.

¶9. (SBU) The drug is normally administered after chemotherapy and radiation treatments have already been performed. Indeed, Fu stressed that patients tend to respond well to a combination of Gendicine and other more traditional treatments. According to Fu, one dose costs USD 420, which is not covered by insurance. While Gendicine treatments are available throughout China, it is most readily available in Beijing hospitals such as the Tumor Hospital and the 301 Military Hospital. Fu commented that convincing doctors to adopt new treatments can be difficult because some doctors (and patients) are reluctant to accept new therapies. Fu said that foreigners have come to China to have the treatment and that some take the drug home with them to continue treatments on their own.

¶10. (SBU) The company reported that the six-year survival rate of a group of twelve patients treated for laryngeal squamous cell carcinoma at middle or late stages is 91.7%. Another clinical trial in which Gendicine was administered to patients with head and neck squamous cell carcinoma showed that the response rate to Gendicine in combination with radiotherapy was 93%; 64% of patients showed complete regression and 29% showed partial regression, according to company literature. (Note: Head and neck squamous cell carcinoma is the second most common skin cancer after basal cell carcinoma, according to Chinese press reports. End note.) Professor Zhang Shanwen of Beijing Cancer Hospital, the chair of Gendicine's phase II clinical trial, told the Chinese press that in combination with chemo- and radiotherapy, Gendicine improved treatment efficacy more than three-fold.

Is Only Chinese Approval Good Enough?

¶11. (SBU) Some scientists have asserted that a looser regulatory environment in China led to the SFDA's approval

of Gendicine. A scientist at the China branch of a foreign drug company said in a 2005 Chinese press report that the fact that China is the only country to have approved commercialized gene therapies makes one question whether China has done enough scientific evaluation. Peng refuted the allegation in the article saying that the SFDA approval for Gendicine is a result of a carefully designed product, the clinical trial plan, the availability of huge patient resources, and the low costs of doing clinical trials in China. According to Chinese press reports, the average cost incurred per patient during clinical trials in the U.S. is about USD 50,000, while Gendicine's trials cost only a fraction of that. The CEO of a state-backed biotech company in Beijing that is developing gene therapy told a U.S. business magazine that he fears that if Gendicine turns out to be ineffective, people will lose faith in all gene therapy.

Beating The Competition Has Its Rewards

¶12. (SBU) Fu estimated that there are approximately ten other Chinese companies working on similar drugs. The director of the Gene Therapy Center at Beijing Haidian Hospital estimated in a Western press report that two dozen Chinese companies are developing gene-therapy drugs. The SFDA has approved three other gene therapy drugs, but SiBiono's was the first to get approval.

¶13. (SBU) One benefit SiBiono had in being the first company to receive approval is that, according to company literature, SiBiono was the main contributor in drafting the "Guidance for Human Gene Therapy Research and Its Products" which was officially issued by the SFDA in March 2003. The guidance provides national guidelines for R&D and commercialization of gene therapy products in China. Fu

noted that the guidelines were basically written by SiBiono because by being the first company to win approval, his company showed they had the most knowledge of the process.

Staff and Training

¶14. (SBU) SiBiono has a staff of roughly 70 people. According to Fu, one-third of the company's employees are medical doctors or have PhD's. Ten percent have work and/or study experience abroad, according to company literature. Fu said most of the company's researchers trained at either the Number One or the Number Four military medical universities. He said the company does not have a hard time retaining MD's or PhD's, but that skilled workers are hard to retain. As a result, the company is currently considering various "perks" to retain workers.

IPR Concerns? Not Really

¶15. (SBU) According to company literature, SiBiono has applied for six patents, two of which have been issued and cover Gendicine and its production methods. SiBiono has trademarked Gendicine and SiBiono worldwide in both Chinese and English. When asked if SiBiono was concerned about applying for a patent -- which requires a company to publicize the procedure -- Fu said the company was not overly concerned because SiBiono holds the core technology which is "not easy to discover." (Note: A U.S. business magazine published a story in March 2006 in which it reported that the CEO and president of U.S. company Introgen said that he believes that his company's patents cover Gendicine -- a view that owner Peng disputed in the story. End Note.) Fu elaborated that the company tries to use the legal protection provided by the patent to protect the drug. On a somewhat related note, Fu mentioned that there is a high-priced black market for the drug on the internet. He speculated that these drugs may be coming from hospitals because so far the drugs they have discovered on the illicit market have been real.

Comment: China's Race to the Technology Finish Line

¶16. (SBU) While Econoffs have no reason (nor the scientific background) to question the efficacy of Gendicine nor the process by which it was approved, recent events in other scientific fields in China reveal the dark side of Chinese innovation. The recent case of disgraced chip developer Chen Jin illustrates the lengths some Chinese scholars will go to to be the "first" to achieve a breakthrough in China, even if it involves cutting corners or outright deception. (Note: Chen became a national hero in 2003 when he said he had created one of China's first digital signal processing computer chips; Chen was disgraced, however, when it was recently revealed that he had faked his research and simply stolen his chip designs from a U.S. company. End Note.) We can only imagine the pressure that "returnees" such as Chen and Peng must certainly face to quickly make major contributions to the motherland, and the government's desire to quickly publicize these accomplishments. It would not surprise us if after the Chen case all future Chinese breakthroughs are given an extra dose of scrutiny and if SiBiono's next round of innovations take a bit longer to be approved, which might not necessarily be a bad thing.

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